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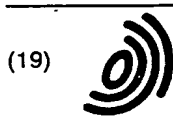
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(54) **System for forming a bifurcated graft**

System zur Herstellung eines abzweigenden Transplantats

Système pour la formation d'une greffe à deux branches

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| WO-A-93/13825 | WO-A-95/21592 |
| DE-U- 9 319 267 | |

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates to a system for forming a bifurcated graft in situ for the treatment of abdominal and other aneurysms.

[0002] Vascular aneurysms are the result of abnormal dilation of a blood vessel, usually resulting from disease and/or genetic predisposition which can weaken the arterial wall and allow it to expand. While aneurysms can occur in any blood vessel, most occur in the aorta and peripheral arteries, with the majority of aortic aneurysms occurring in the abdominal aorta, usually beginning below the renal arteries and often extending distally into one or both of the iliac arteries.

[0003] Aortic aneurysms are most commonly treated in open surgical procedures where the diseased vessel segment is bypassed and repaired with an artificial vascular graft. While considered to be an effective surgical technique, particularly considering the alternative of a usually fatal ruptured abdominal aortic aneurysm, conventional vascular graft surgery suffers from a number of disadvantages. The surgical procedure is complex and requires experienced surgeons and well equipped surgical facilities. Even with the best surgeons and equipment, however, patients being treated frequently are elderly and weakened from cardiovascular and other diseases, reducing the number of eligible patients. Even for eligible patients prior to rupture, conventional aneurysm repair has a relatively high mortality rate, usually from 3% to 10%. Morbidity related to the conventional surgery includes myocardial infarction, renal failure, impotence, paralysis, and other conditions. Additionally, even with successful surgery, recovery takes several weeks, and often requires a lengthy hospital stay.

[0004] In order to overcome some or all of these drawbacks, endovascular graft placement for the treatment of aneurysms has been proposed. Although very promising, many of the proposed methods and apparatus suffer from other problems. Often times the proposed graft structures will have exposed anchors or frame which can be thrombogenic. It is also difficult to provide graft structures which remain sealed to the blood vessel lumen to prevent the leakage or bypass of blood into the weakened aneurysm, especially when subjected to external deforming forces which result from vessel expansion and contraction as the heart beats. Many vascular graft structures have difficulty in conforming to the internal arterial wall, particularly since the wall can have a highly non-uniform surface as a result of atherosclerosis and calcification and is expanding and contracting with the patient's heartbeat and blood flow. Additionally, many previous vascular graft structures are difficult to position and anchor within the target region of the ves-

sel.

[0005] For these reasons, it would be desirable if the graft structures were easy to place in the target region, displayed little or no thrombogenicity, provided a firm seal to the vascular wall to prevent leakage and blood bypass, and were able to conform to uniform and non-uniform blood vessel walls, even while the wall is expanding and contracting with the patient's heartbeat.

2. Description in the Background Art

[0006] Vascular grafts and devices for their transluminal placement are described in U.S. Patent Nos. 5,219,355; 5,211,658; 5,104,399; 5,078,726; 4,820,298; 4,787,899; 4,617,932; 4,562,596; 4,577,631; and 4,140,126; and European Patent Publications 508 473; 466 518; and 461 791.

[0007] Expandable and self-expanding vascular stents are described in U.S. Patent Nos. 5,147,370; 4,994,071; and 4,776,337; European patent Publications 575 719; 556 850; 540 290; 536 610; and 481 365; and German patent Publication DE 42 19 949. A flexible vascular stent structure having counter wound helical elements, some of which are separated at particular locations to enhance flexibility, is commercially available from Angiomed, Karlsruhe, Germany, as described in a brochure entitled Memotherm Iliaca Stents.

[0008] Catheters for placing vascular stents are described in U.S. Patent Nos. 5,192,297; 5,092,877; 5,089,005; 5,037,427; 4,969,890; and 4,886,062.

[0009] DE-U-9319267 discloses a system for forming a bifurcated graft in situ comprising a base structure including a proximal anchor and two distally located holes thus defining a common flow lumen and a pair of flow paths diverging from said lumen. Two tubular grafts can be anchored within the base structure to form continuous extensions of the diverging flow lumens.

SUMMARY OF THE INVENTION

[0010] The present invention provides a system according to claim 1 for the *in situ* placement of bifurcated grafts for the treatment of aorto-iliac segments and other bifurcated lumens. A preferred system comprises a bifurcated base structure including a proximal anchor, typically a self-expanding frame, which defines a common flow lumen and a pair of connector legs that establish divergent flow lumens from the common flow lumen. The preferred system also includes a first tubular graft which can be anchored within first of the connector legs to form a continuous extension of the first divergent flow lumen and a second tubular graft which can be anchored within a second of the connector legs to form a continuous extension of the second divergent flow lumen. A preferred method of placement comprises first introducing the bifurcated base structure so that the anchor section is positioned within a primary vessel, i.e., the aorta, below the renal arteries. After the bifurcated

base structure is anchored, the first tubular graft is introduced into the first connector leg and anchored between said leg and the first branch artery, e.g., the right iliac. The second tubular graft is then inserted into the second connector section and anchored between the second connector and the second branch artery. By properly selecting the dimensions of the bifurcated base structure, the first tubular graft, and the second tubular graft, the resulting bifurcated graft structure can have dimensions which are specifically matched to the vessel dimensions being treated. Preferably, the bifurcated base structure, first tubular graft, and second tubular graft, will be formed from radially compressible perforate tubular frames having interior and/or exterior liners, generally as described above for the preferred vascular graft of the present invention. The radially compressible perforate tubular frame on the base structure, however, will terminate above the region where the connector legs diverge. The connector legs below the divergent region will be reinforced by placement and expansion of the tubular graft structures therein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Fig. 1 is a side view of a vascular graft for the system in accordance with the principles of the present invention.

[0012] Fig. 1A is a side view of a first alternate embodiment of a vascular graft.

[0013] Fig. 1B is a side view of a second alternate embodiment of a vascular graft.

[0014] Fig. 2 is a side view of a radially compressible perforate tubular frame of a type which may be used in a vascular graft of Fig. 1.

[0015] Figs. 3A and 3B are a schematic illustrations showing the joining pattern of the radially compressible band members of the tubular frame of Fig. 2.

[0016] Fig. 4 illustrates a structure which has been etched from a tube and which may be subsequently expanded to form the tubular frame of Fig. 2.

[0017] Fig. 5 illustrates a bifurcated base structure which is part of a system for forming a bifurcated graft *in situ* in accordance with the principles of the present invention.

[0018] Fig. 6 illustrates the distal end of a graft and stent placement catheter.

[0019] Figs. 7-12 illustrate placement of a bifurcated aortic graft using the bifurcated graft placement system of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENT

[0020] The present invention provides a system for forming a bifurcated graft *in situ* for the transluminal placement of graft structures, particularly within the vascular system for treatment of aneurysms and other vascular conditions, but also in other body lumens, such as ureter, urethra, biliary tract, gastrointestinal tract, and

the like, for the treatment of other conditions which benefit from the introduction of a reinforcing or protective structure in the lumen. The system can also find use in the creation of artificial lumens through solid tissue and structures, such as the placement of a TE fistula via an endoscope. The vascular grafts will be placed endovascularly. As used herein, "endovascularly" will mean placement by percutaneous or cutdown transluminal procedures using a catheter over a guidewire under fluoroscopic guidance. The catheters and guidewires may be introduced through conventional access sites to the vascular system, such as through the brachial and subclavian arteries for access to the aorta and through the femoral arteries for access to the aorta or to peripheral and branch blood vessels.

[0021] Referring to Figs. 1-4, an exemplary graft structure 10 will be described which is used a system for forming a bifurcated graft *in situ* according to the invention. The graft structure 10 includes a fabric liner 12 and a radially compressible perforate tubular frame 14. For convenience, the frame 14 is illustrated by itself in Fig. 2. The frame is illustrated in its expanded (relaxed) configuration in each of these figures, but may be radially compressed by applying a radially inward compressive force, usually by placing the graft 10 in an outer sheath, as will be described in more detail hereinafter.

[0022] The tubular frame 14 comprises a plurality of radially compressible band members 11, each of which comprises a zig-zag or Z-shaped element which forms a continuous circular ring. Each band member 11 will typically have a width w in the range from 2 mm to 15 mm, and the tubular frame will comprise from 1 to 30 individual band members. Adjacent band members 11 are preferably spaced-apart from each other by a short distance d and are joined by bridge elements 13. Flexibility is enhanced by providing only two diametrically opposed bridge elements 13 between each adjacent pair of band members 11. As will be described further with reference to Fig. 1A, flexibility can be further enhanced by leaving the band members connected only by the liner.

[0023] Usually, the perforate tubular frame 14 will be left open at each end, e.g., at least a portion of the last band member 11 will remain uncovered by the liner 12.

The liner 12 will be stitched or otherwise secured to the band members 11, preferably at the junctions or nodes when the element reverses direction to form the Z-pattern (although the stitching should not cross over between the band members in a way that would restrict flexibility). The liner 12 will usually pass outward from the inner lumen of the tubular frame 14 to the exterior of the frame through the gap between adjacent band members, as illustrated in Fig. 1. The portion of liner 12 on the exterior of the tubular frame 14 helps seal the end(s) of the graft 10 against the wall of the blood vessel or other body lumen in which it is disposed.

[0024] The joining pattern of adjacent band members 11 is best illustrated in Figs. 3A and 3B. Fig. 3A illus-

trates the tubular frame 14 as it would look if unrolled onto a flat surface. Fig. 3B is similar to Fig. 3A, except that the band members are expanded. The expansion is shown at 30°, but will frequently extend up to 60° or higher in use.

[0025] A preferred method for forming the tubular frame 14 may be described with reference to Fig. 4. A tube of the desired elastic material, such as nickel titanium alloy having a phase transformation temperature significantly below 37°C, preferably between 30°C and 32°C, is obtained. The tube will have dimensions roughly equal to the desired dimensions of the frame when radially compressed. The tube may be drawn, rolled, or otherwise treated to achieve the desired wall thickness, diameter, and the like. Suitable wall thicknesses are in the range of about 0.1 mm to 0.5 mm. A pattern of axial slots is then formed in the tube, as illustrated in Fig. 4. The slots may be formed by electrical discharge machining (EDM), photochemical etching, laser cutting, machining or other conventional techniques. After the slots have been formed, the tube is mechanically expanded to its desired final (relaxed) diameter and heat treated at a suitable temperature to set the tube in the desired expanded state. Sharp edges are removed by conventional techniques, such as deburring, abrasive extrusion, or the like. The result of the expansion is the tubular frame illustrated in Figs. 1 and 2.

[0026] Preferably, each end of the liner 12 will be circumferentially sealed at or near the distal and proximal ends of the tubular graft. As illustrated in Fig. 1A, this can be achieved by folding over the end of the liner 12 onto the external surface of the graft 10. Conveniently, this can be done through the gaps which are present between adjacent band members 14. Where the junctions 13 remain, the liner 12 can be carefully stitched onto the underlying surface of the frame, as shown at 18 in Fig. 1A. Other techniques for circumferentially sealing the liner include heat or ultrasonic welding of the liner, laminating an outer gasket, sewing an outer reinforcement member, or the like.

[0027] Referring now to Fig. 1A, an alternative embodiment 100 of a vascular graft will be described. The graft 100 comprises a perforate tubular frame 102 which includes a plurality of independent (non-connected) band members 104 separated from each other by gaps 106. The perforate tubular frame 102 is similar in construction to frame 14 of graft 10, except that adjacent band members 104 are not directly connected to each other. Band members 104 will be connected only by an inner liner 108 and an outer liner 110, where the inner and outer liners together encase or sandwich the otherwise free-floating band members 104. In order to secure the band members 104 in place, and secure the liners to the perforate tubular frame 102, the inner and outer liners are joined together along circumferential lines 112, preferably located in the gaps 106 between adjacent band members 104. The liners may be joined together by stitching, heat welding, ultrasonic welding, or

the like. In the exemplary embodiment, the liners 108 and 110 are formed from polymeric sheet material and are joined together by ultrasonic welding. The band members 104 at each end of the graft 100 will have to be further secured to the liners 108 and 110. For example, they could be stitched, welded, or otherwise joined to the liners to hold them in place. The dimensions, materials, and other aspects of the graft 100 will be generally the same as those described previously for graft 10.

[0028] Referring now to Fig. 1B, a second alternative embodiment 200 of the vascular graft. The graft 200 comprises a perforate tubular frame 202 including a plurality of laterally compressible axial members 204. Each axial member 204 comprises a plurality of diamond-shaped structural elements which are connected to each other in a linear fashion. It will be appreciated that each diamond-shaped structural element is laterally compressible so that the frame 202 as a whole may be radially compressed from a reduced-diameter configuration to an expanded-diameter configuration. As illustrated in Fig. 1B, the frame is in a partially compressed configuration. The axial members 202 will be captured between an inner liner 206 and an outer liner 208. The inner liner 206 and outer liner 208 will be secured to each other along a plurality of axial lines 210 disposed between adjacent axial members 204. In this way, each axial member 204 will be captured within a pocket formed between the inner liner 206 and outer liner 208. As with previous embodiments, the ends of the frame may extend beyond the liners to provide for improved anchoring and perfusion on either side of the graft.

[0029] Referring now to Fig. 5, a bifurcated base structure for forming a bifurcated graft in combination with a pair of the vascular grafts 10 just discussed will be described. The bifurcated base structure 20 comprises an anchor segment 22, which typically will be a radially compressible perforate frame having a structure similar or identical to that just discussed. The frame of anchor 22 will typically have a length in the range from about 5 mm to 50 mm, and a diameter in the range from about 5 mm to 30 mm. A liner 24 will be disposed within the frame 22, typically being circumferentially sealed near the upper end of the frame, e.g., being folded over and stitched as described previously. As with the straight graft embodiment of Figs. 1-4, the proximal end of the liner 24 will preferably be distally spaced-apart from the proximal end of the anchor segment 22, typically by a distance in the range from 1 mm to 25 mm. The fabric 24 defines a common flow lumen at its upper end and a pair of divergent flow lumens at its lower end, one in each leg 26 and 28. The legs 26 and 28 are preferably not covered by the frame of anchor 22. The fabric legs 26 and 28 will each have a diameter in the range from 6 mm to 18 mm and a length in the range from 5 mm to 30 mm. The dimensions of each leg need not be the same.

[0030] Referring now to Fig. 6, a catheter 30 for delivering the vascular graft 10 or bifurcated base structure

20 will be described. The catheter 30 includes a shaft 32 having a pair of axially spaced-apart stays 34 and 36. A pull wire 38 extends through a lumen 40 of shaft 32 and through protrusions on each of the stays 34 and 36. A sheath 42 is slidably disposed over the shaft 32 so that it may be advanced over the stays 34 and 36. Guidewire 34 extends through the shaft 32 and shaft extension 46 to facilitate vascular introduction of the catheter 30. A radially compressible graft G (such as graft 10) is placed over the distal end of the shaft extension 46, generally being aligned between the stays 34 and 36. The pull wire 38 is then advanced through the stays 34 and 36 so that it passes through each end of the graft G to maintain the graft in place until the pull wire is withdrawn. While the pull wire 38 remains in place, the sheath 42 may be axially advanced over the graft to radially compress the graft into its desired low profile diameter. The sheath 42 includes a flared (*i.e.*, outwardly tapered) distal end 46 to facilitate advancing the sheath over the graft, in particular so that the graft may be recaptured when it is partially deployed, as described hereinafter. The outward taper may be permanently fixed in the body of the sheath, but will preferably be selectively deployable between the tapered configuration and a non-tapered or straight configuration (shown in broken line) to facilitate introduction of the sheath through the vasculature or other body lumen. A variety of suitable mechanisms for selectively expanding the distal end of the sheath are known in the art, such as pull wires and the like. The sheath 42 will be introduced through the vasculature through a conventional introducer sleeve having a proximal hemostasis valve.

[0031] The catheter 30 may be modified to provide alternate delivery techniques for the graft G. For example, the catheter 30 may include a balloon at or near its distal end for use with grafts having malleable portions which need to be expanded. The catheter 30 might also include bumpers or other means for aligning the graft on the shaft 46 while the sheath 42 is being retracted. A variety of other catheter constructions and techniques for delivering the radially-compressible graft and stent structures of the present invention.

[0032] Referring now to Figs. 7-12, placement of a bifurcated graft structure in an abdominal aortic aneurysm AA of a patient will be described. Initially, the delivery catheter 30 is introduced through an introducer sleeve 50 via an antegrade approach (e.g. the subclavian artery SC), as illustrated in Fig. 7. The bifurcated base structure is initially maintained within sheath 42 so that it remains radially compressed. After the compressed base structure 20 is properly positioned, the sheath 42 will be withdrawn, allowing the base structure 20 to expand in place, as illustrated in Fig. 8. The catheter 30 may then be withdrawn, leaving the guidewire GW in place. A vascular graft 10 is then mounted on the catheter 30 and reintroduced so that the compressed vascular graft lies within the fabric liner leg 28 while covered with sheath 42, as illustrated in Fig. 9. The sheath 42 is

then withdrawn so that the vascular graft 10 will expand both within the leg 28 and the left iliac LI, as illustrated in Fig. 10. The catheter 30 is then withdrawn, and the guidewire is transferred from the left iliac LI to the right iliac RI. Alternatively, a separate guidewire could be introduced. Catheter 30 is then reintroduced over the guidewire with sheath 42 covering a second vascular graft 10 and advanced into the right iliac, as illustrated in Fig. 11. The sheath 42 is then withdrawn, allowing the second vascular graft 10 to expand within both the right iliac RI and the second leg 26 of the fabric liner. The completed bifurcated graft structure is then in place, as illustrated in Fig. 12, and the guidewire GW, catheter 30, and introducer sheath 50 may then be withdrawn.

[0033] Femoral access and retrograde placement of the graft structures of the present invention will be possible although such an approach is not presently preferred.

[0034] Positioning and repositioning of the stent-graft structure of the present invention can be facilitated by use of an ultrasonic imaging catheter or guidewire, such as the guidewires described in U.S. Patent Nos. 5,095,911 and PCT WO 93/16642. Such ultrasonic guidewires can be used in place of the conventional guidewire 30 illustrated in Figs. 7-12, typically being sealed by a hemostasis valve at the proximal end of the delivery catheter 30. Locking means, clamps, markings, and the like, may be provided on either or both of the delivery catheter 30 and the imaging guidewire to assure proper positioning of the ultrasonic transducer within the stent-graft structure during the placement procedure. The aneurysm or other anomaly being treated can then be precisely located prior to release of the stent-graft 10. After partial placement, proper location of the stent-graft 10 can be confirmed with the ultrasonic imaging device. If the position is not correct, the stent-graft 10 can be drawn back into the sheath 42, and the stent-graft be repositioned prior to complete release. The use of an ultrasonic imaging guidewire is advantageous since there is no need to exchange the guidewire for a separate ultrasonic imaging catheter.

[0035] Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

Claims

1. A system for forming a bifurcated graft in situ, said system comprising
 - a base structure (20) including a proximal anchor (22) and defining a common flow lumen and a pair of flow paths divergent from the common flow lumen; and first and second tubular grafts (10, 100, 200) which can be anchored within the base structure (20) to form continuous extensions of the diver-

gent flow paths;

characterized in that

said base structure (20) is bifurcated to provide said divergent flow paths within a pair of connector legs (26, 28) defining divergent flow lumens, whereby said first and second tubular grafts (10) can be anchored respectively within said connector legs (26, 28), and in that said base structure (20) comprises a liner (24) secured with said anchor (22).

2. A system as in claim 1, characterized in that said first and second tubular grafts (10, 100, 200) are internally lined with a graft liner (12, 106, 206).
3. A system as in claim 1 or 2, characterized in that the anchor (22) of the bifurcated base structure (20) comprises a radially compressible perforate tubular frame in which the liner (24) is disposed, and wherein at least one of the first and second tubular grafts (10, 100, 200) comprises a radially compressible perforate tubular frame (14, 102, 202) in which a graft liner is disposed extending over an interior lumen surface of the tubular frame (14, 102, 202).

Patentansprüche

1. System zum Bilden eines bifurkationsförmigen Transplantats in situ, wobei das System umfaßt:
eine Basisstruktur (20), die einen proximalen Anker (22) enthält und ein gemeinsames Strömungslumen und ein Paar vom gemeinsamen Strömungslumen divergierende Strömungswege definiert; und ein erstes und ein zweites röhrenförmiges Transplantat (10, 100, 200), die innerhalb der Basisstruktur (20) verankert werden können, um kontinuierliche Verlängerungen der divergierenden Strömungswege zu bilden;
dadurch gekennzeichnet, daß
die Basisstruktur (20) bifurkationsförmig ist, um die divergierenden Strömungswege innerhalb eines Paares Verbindungsschenkel (26, 28) vorzusehen, die divergierende Strömungslumen definieren, wodurch die ersten und zweiten röhrenförmigen Transplantate (10) jeweils in den Verbindungsschenkeln (26, 28) verankert werden können, und daß die Basisstruktur (20) eine am Anker (22) befestigte Verkleidung (24) umfaßt.
2. System nach Anspruch 1, dadurch gekennzeichnet, daß die ersten und zweiten röhrenförmigen Transplantate (10, 100, 200) innen mit einer Transplantatverkleidung (12, 106, 206) ausgekleidet sind.
3. System nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß der Anker (22) der bifurkationsförmigen Basisstruktur (20) ein radial zusammendrück-

bares, perforiertes, röhrenförmiges Gerüst aufweist, in dem die Verkleidung (24) angeordnet ist, wobei wenigstens eines der ersten und zweiten röhrenförmigen Transplantate (10, 100, 200) ein radial zusammendrückbares, perforiertes, röhrenförmiges Gerüst (14, 102, 202) umfaßt, in dem eine Transplantatverkleidung angeordnet ist, die sich über eine innere Lumenoberfläche des röhrenförmigen Gerüsts (14, 102, 202) erstreckt.

Revendications

1. Système destiné à former un implant dédoublé in situ, ledit système comprenant:
une structure de base (20) comportant une attache proximale (22) et définissant une lumière d'écoulement commune et une paire de trajets d'écoulement divergents par rapport à la lumière d'écoulement commune; et des premier et second implants tubulaires (10, 100, 200) qui peuvent être fixés à l'intérieur de la structure de base (20) afin de former des extensions continues des trajets d'écoulement divergents;
caractérisé en ce que:
ladite structure de base (20) est dédoublée de manière à former lesdits trajets d'écoulement divergents à l'intérieur d'une paire de branches de raccordement (26, 28) définissant des lumières d'écoulement divergentes, de telle sorte que lesdits premier et second implants tubulaires (10) peuvent être fixés respectivement à l'intérieur desdites branches de raccordement (26, 28), et en ce que ladite structure de base (20) comprend une enveloppe (24) fixée à ladite attache (22).
2. Système selon la revendication 1, caractérisé en ce que lesdits premier et second implants tubulaires (10, 100, 200) sont munis d'une doublure intérieure formée d'une enveloppe d'implant (12, 106, 206).
3. Système selon la revendication 1 ou 2, caractérisé en ce que l'attache (22) de la structure de base dédoublée (20) comprend une structure tubulaire perforée pouvant être compressée radialement dans laquelle est disposé l'enveloppe (24), et dans lequel au moins un des premier et second implants tubulaires (10, 100, 200) comprend une structure tubulaire perforée pouvant être compressée radialement (14, 102, 202) dans laquelle est disposée une enveloppe d'implant recouvrant une surface de lumière intérieure de la structure tubulaire (14, 102, 202).

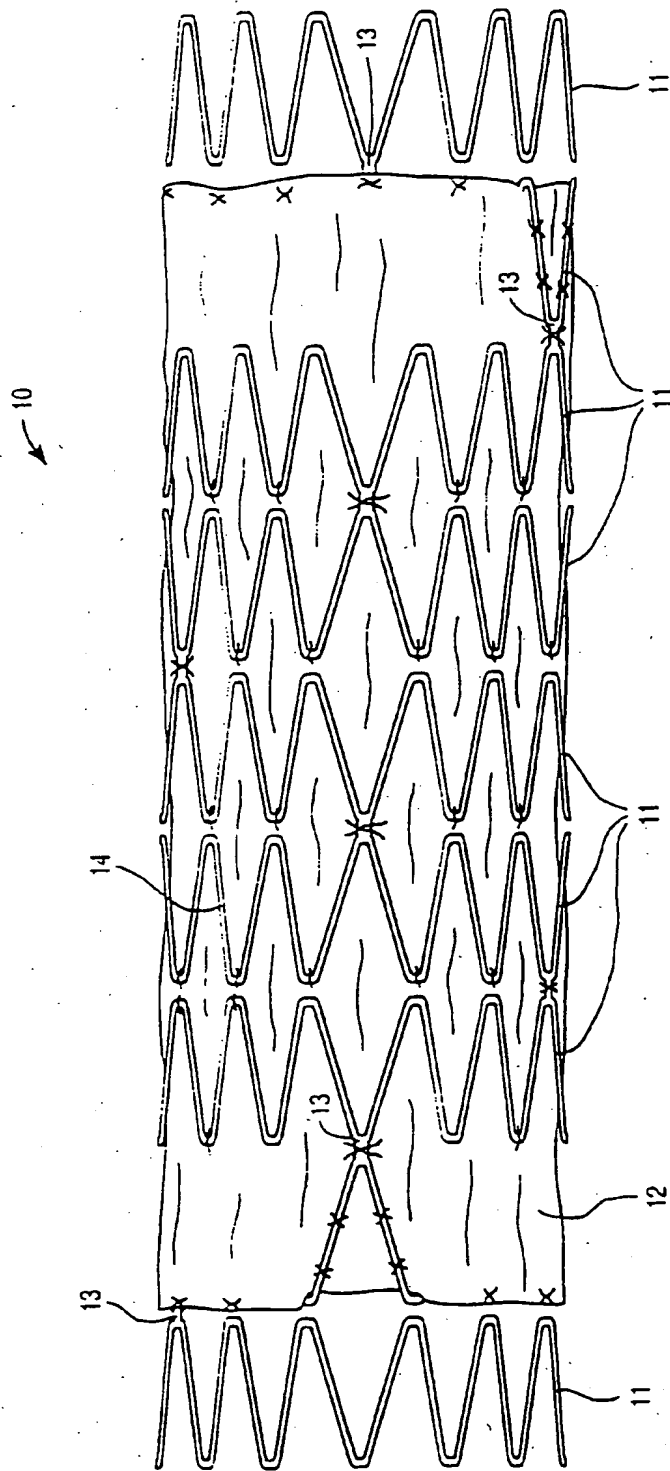


FIG. 1

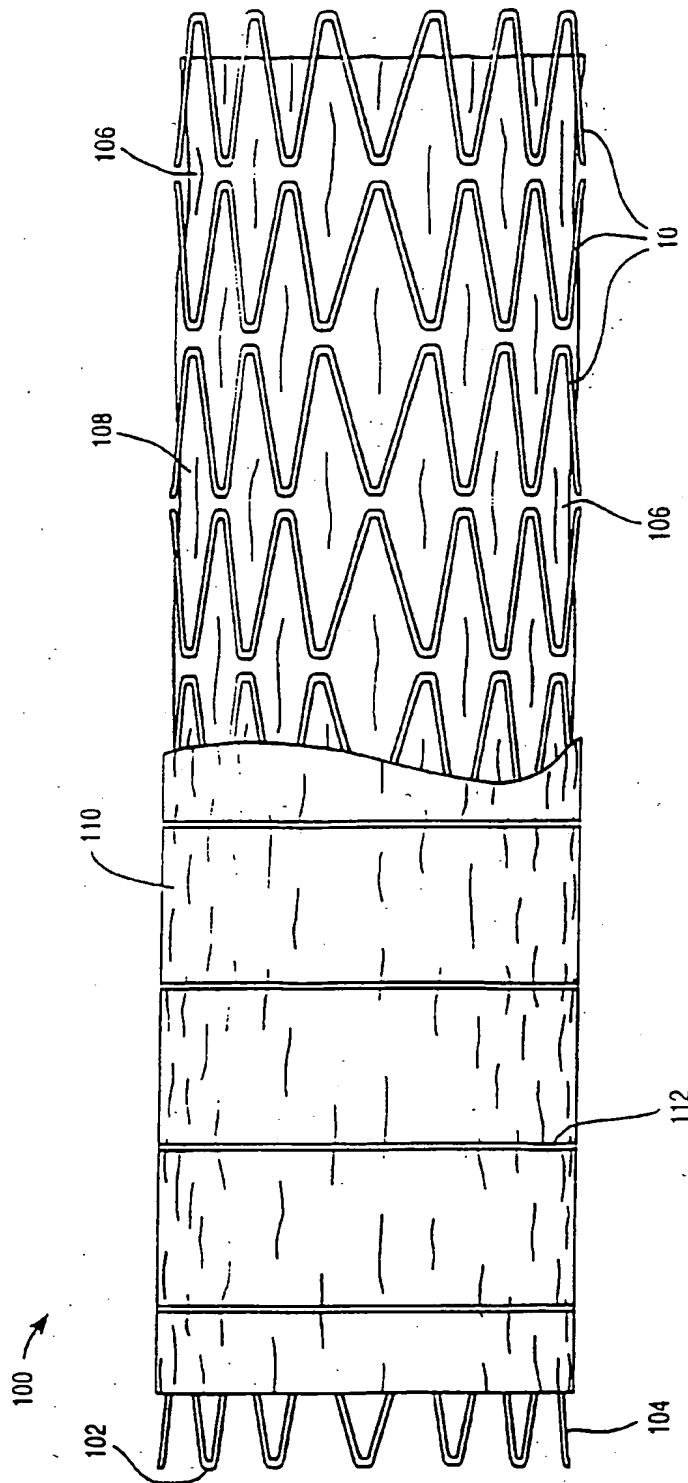


FIG. 1A

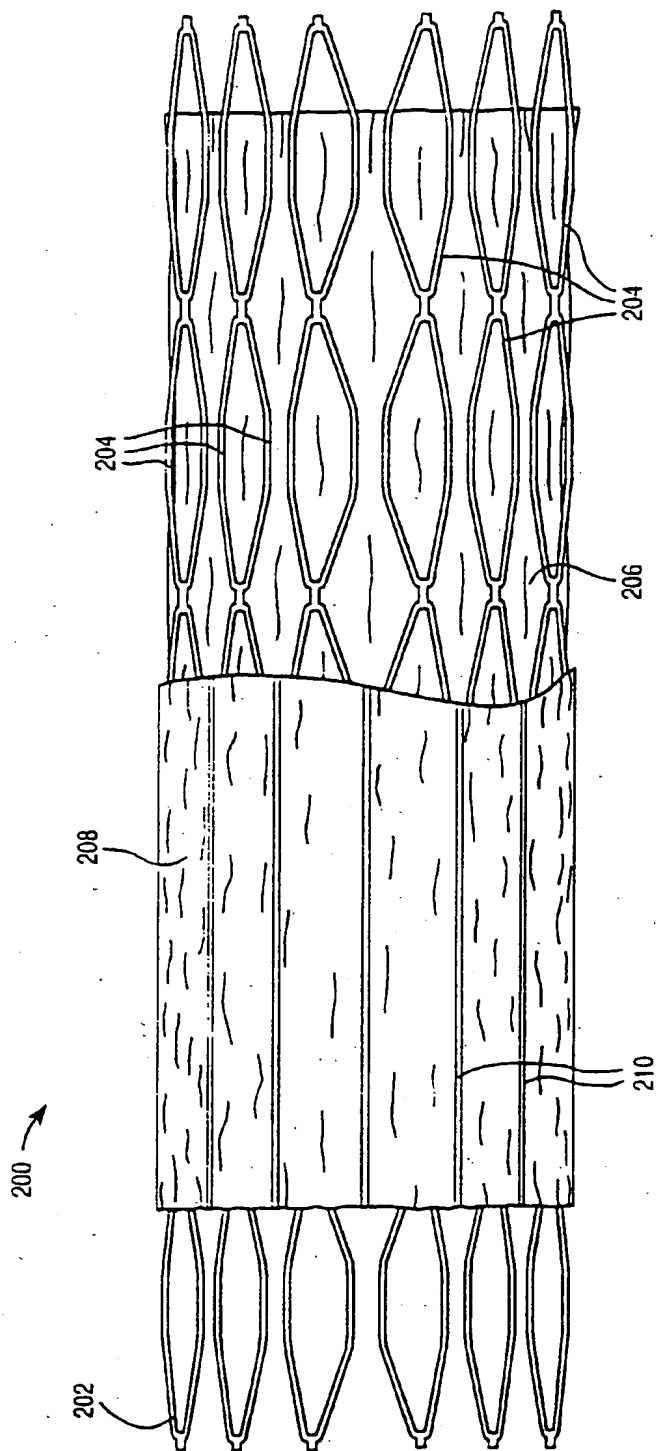


FIG. 1B

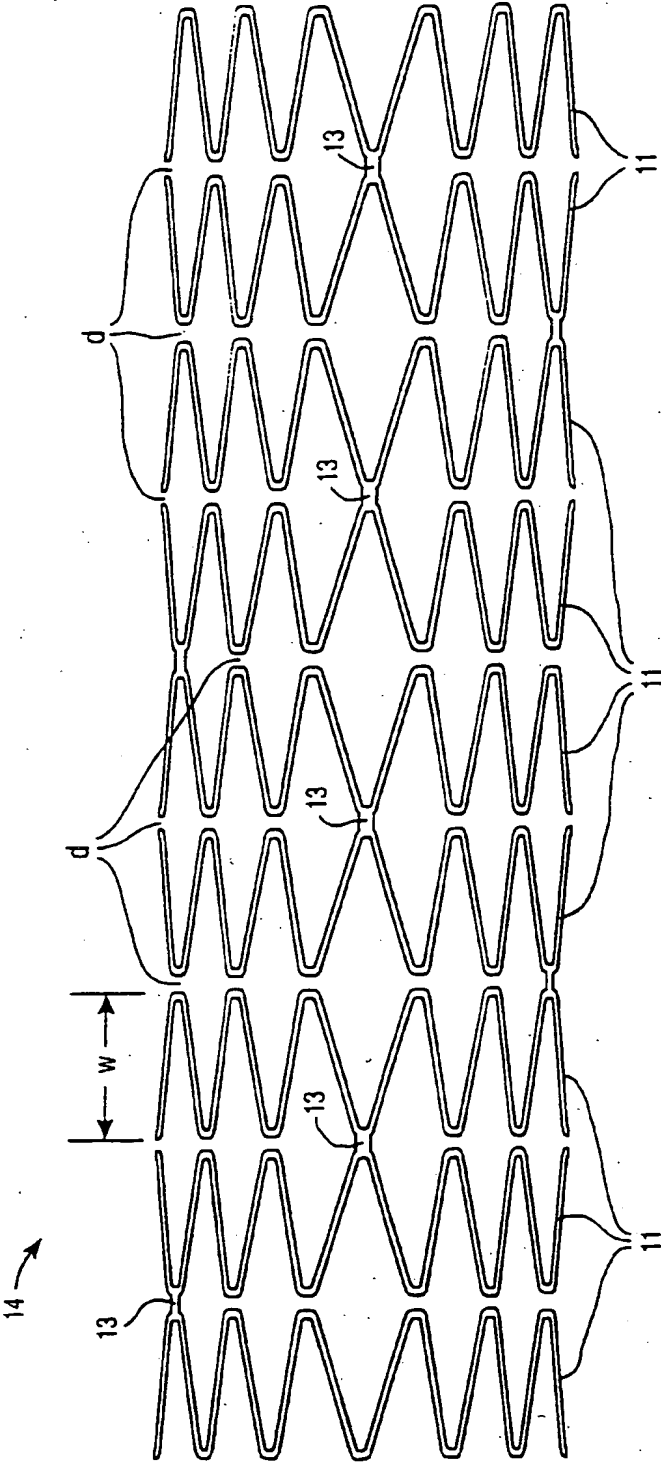


FIG. 2

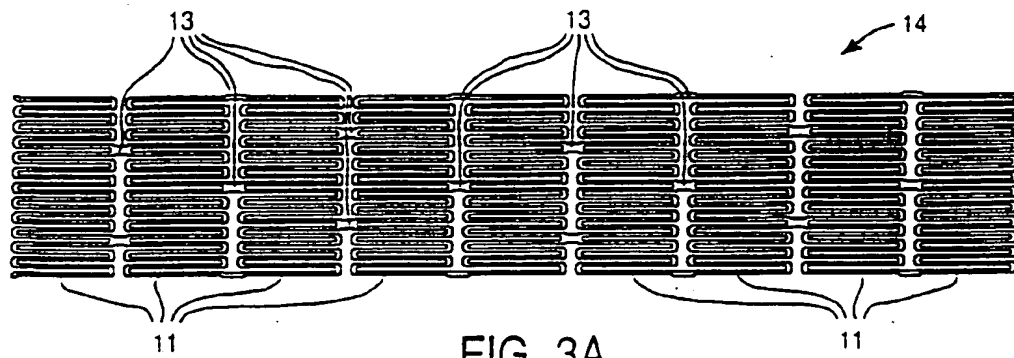


FIG. 3A

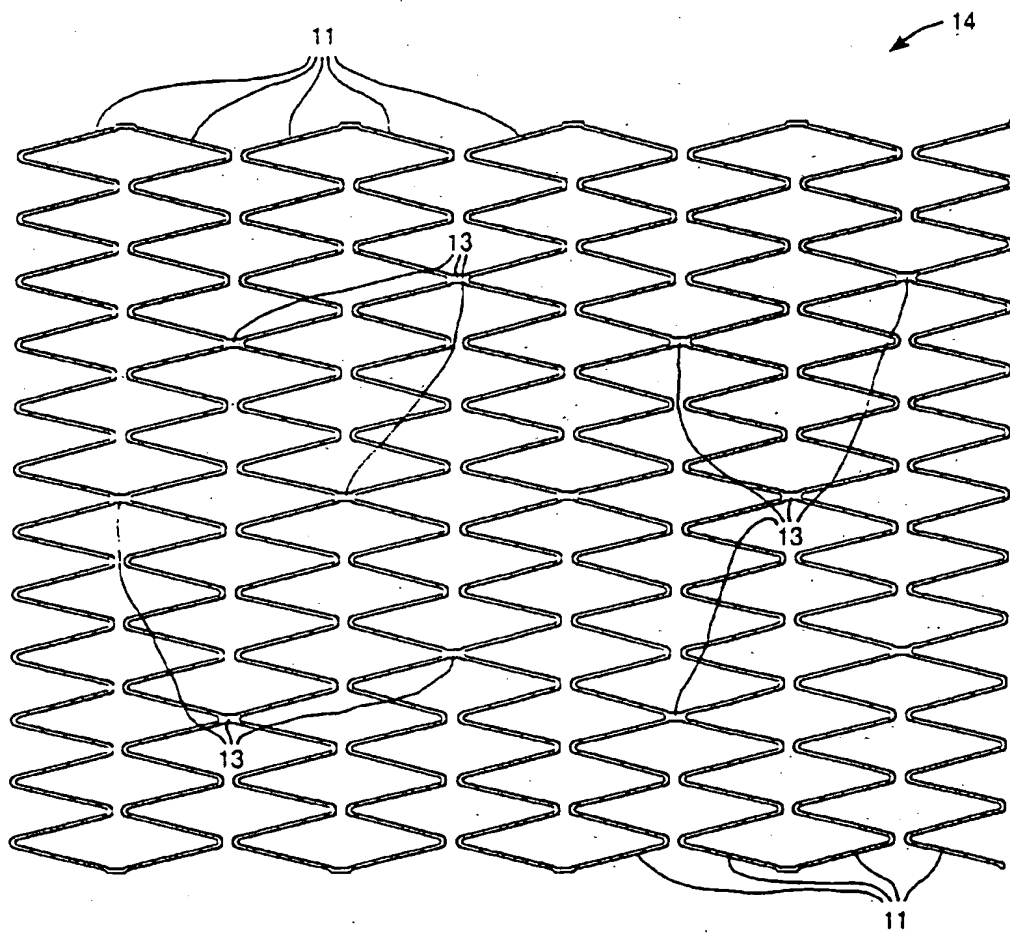


FIG. 3B

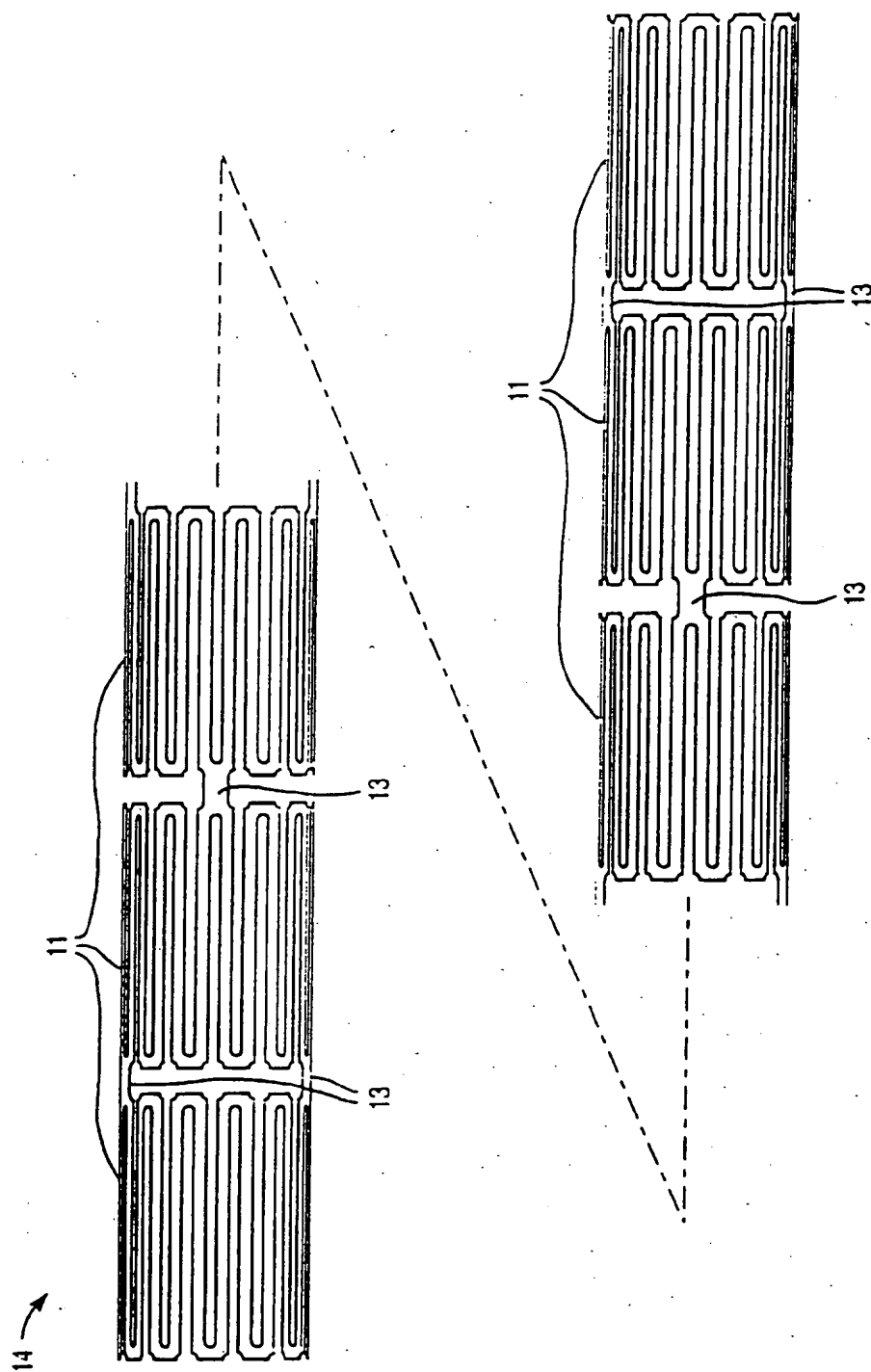


FIG. 4

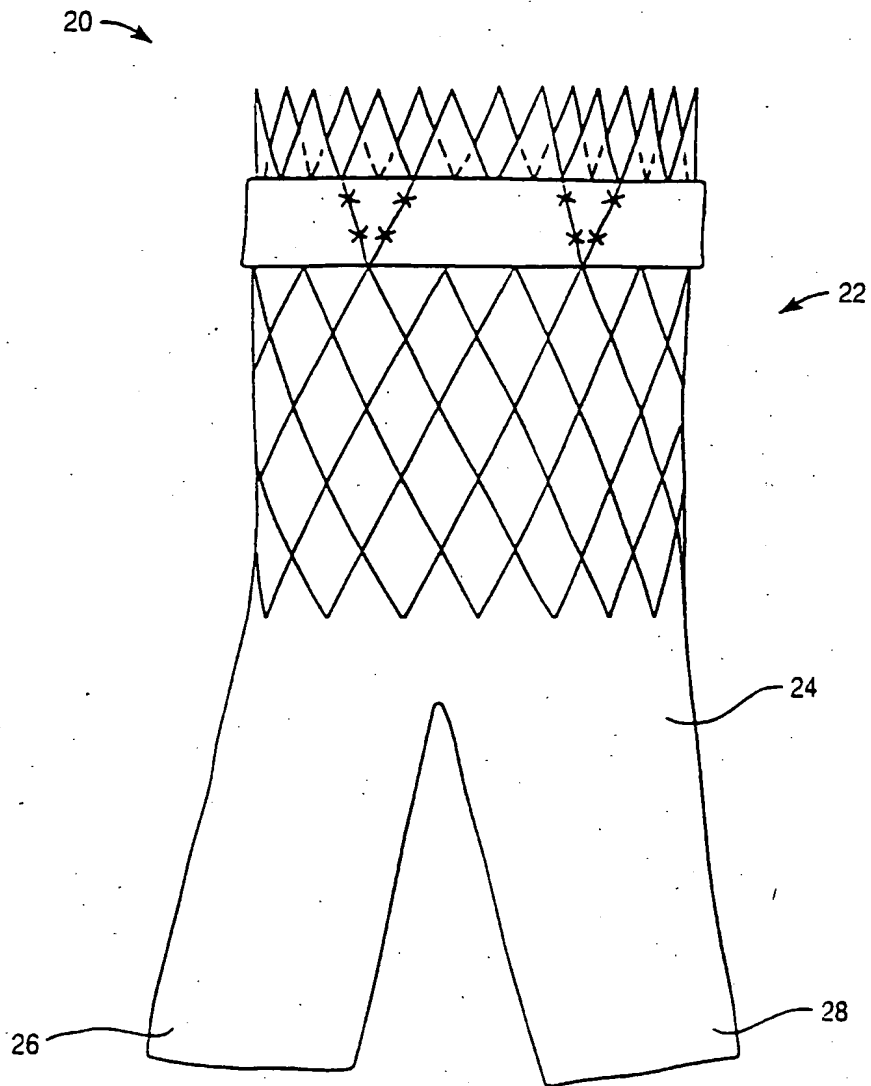


FIG. 5

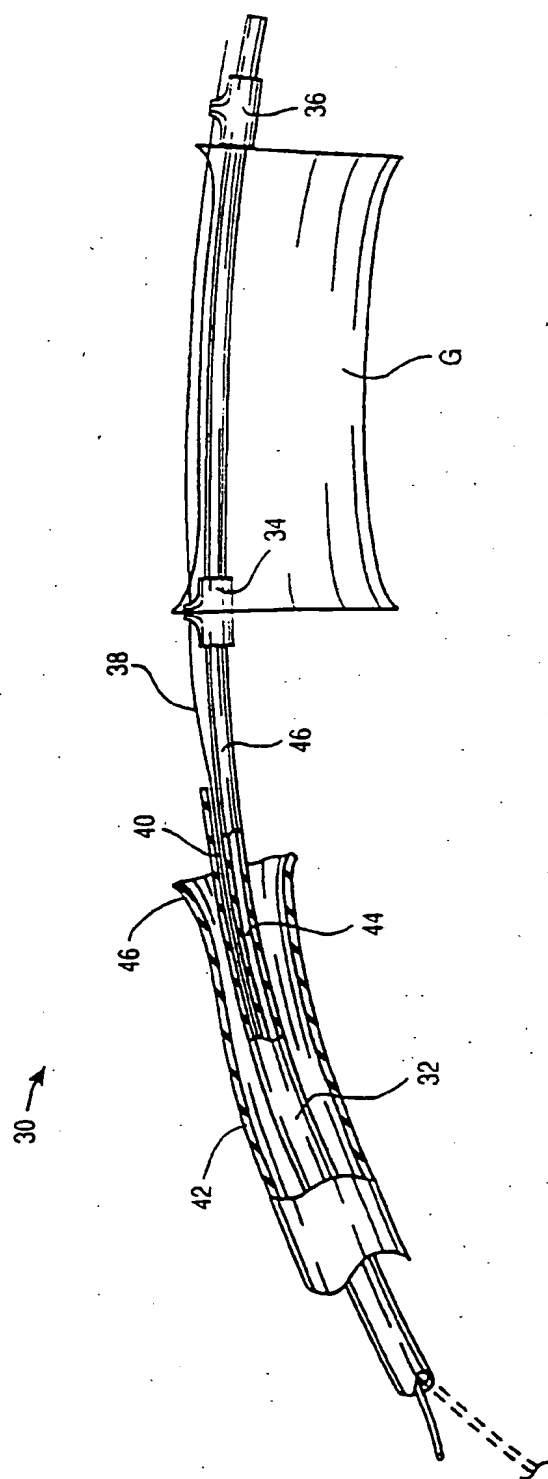


FIG. 6

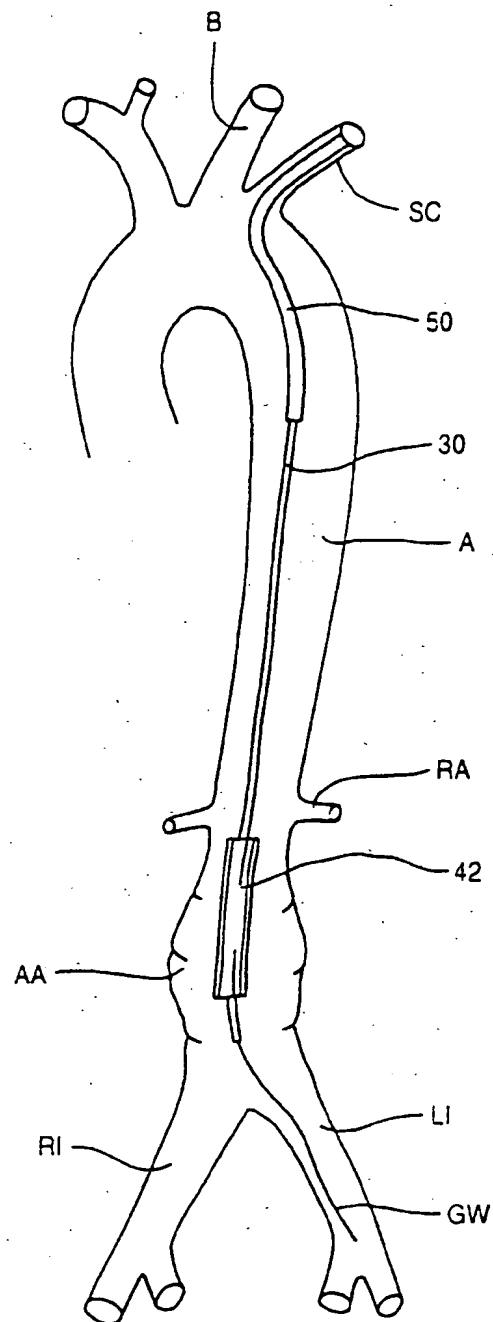


FIG. 7

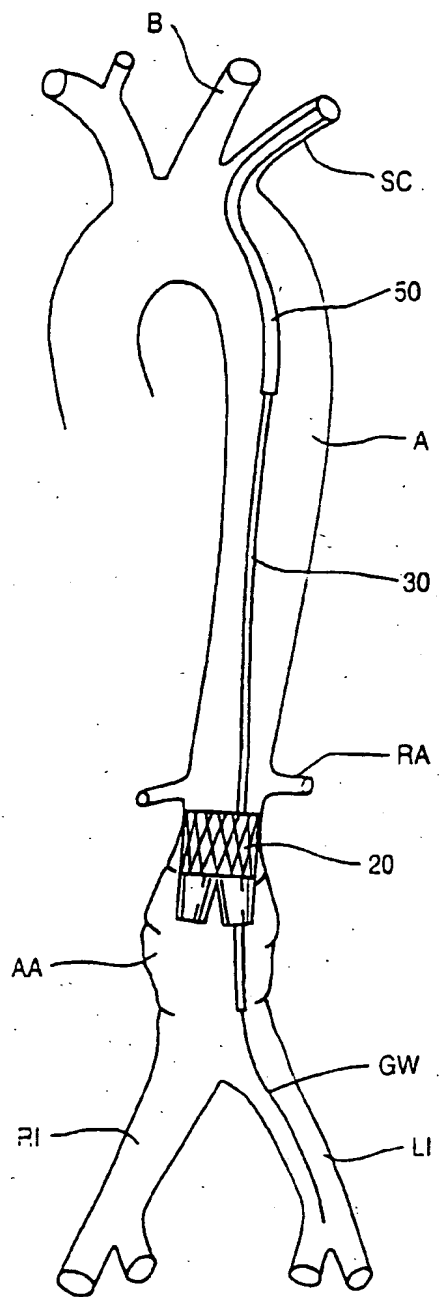


FIG. 8

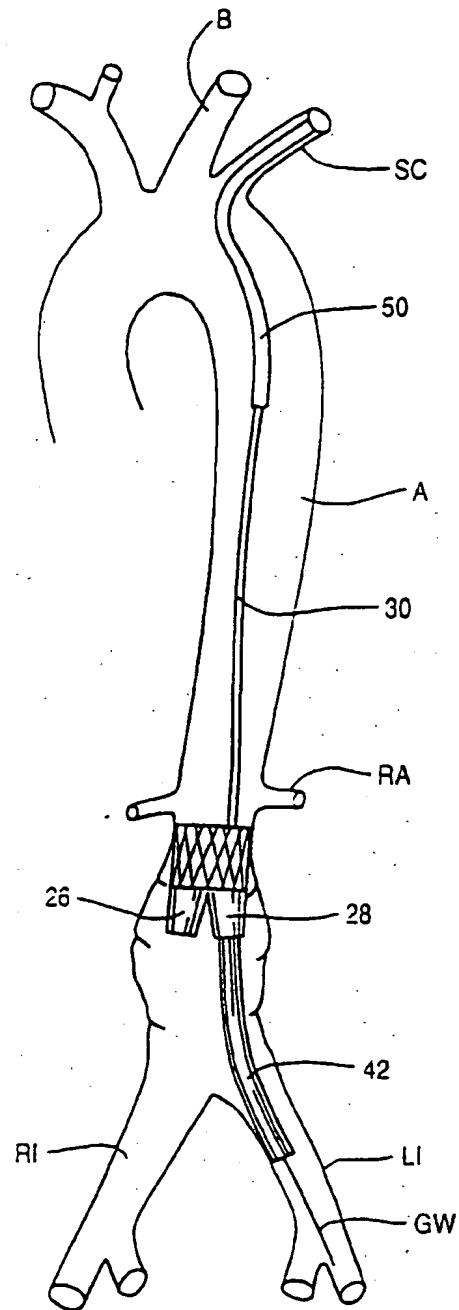


FIG. 9

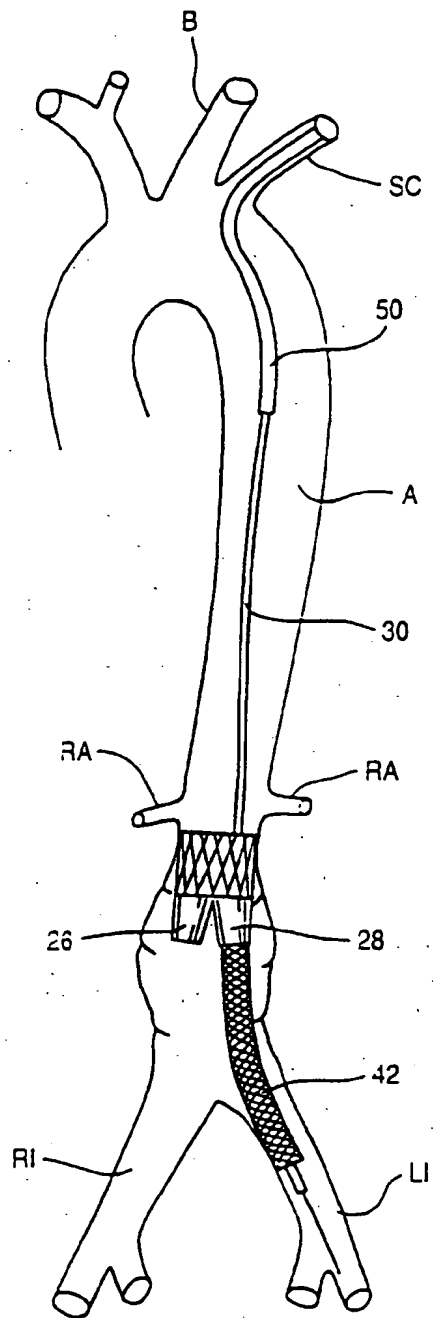


FIG. 10

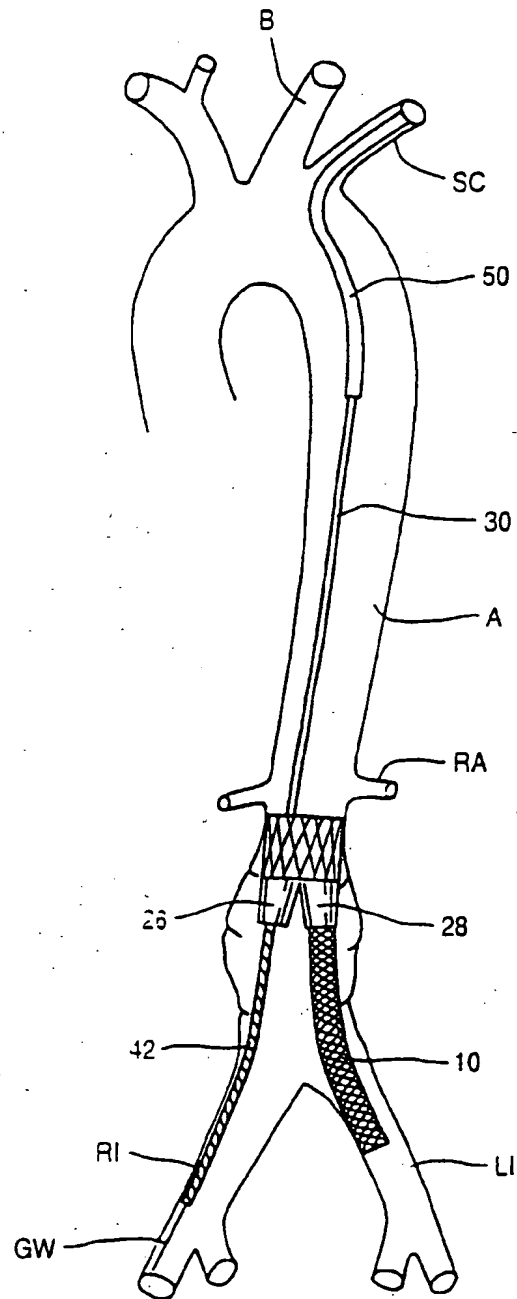


FIG. 11

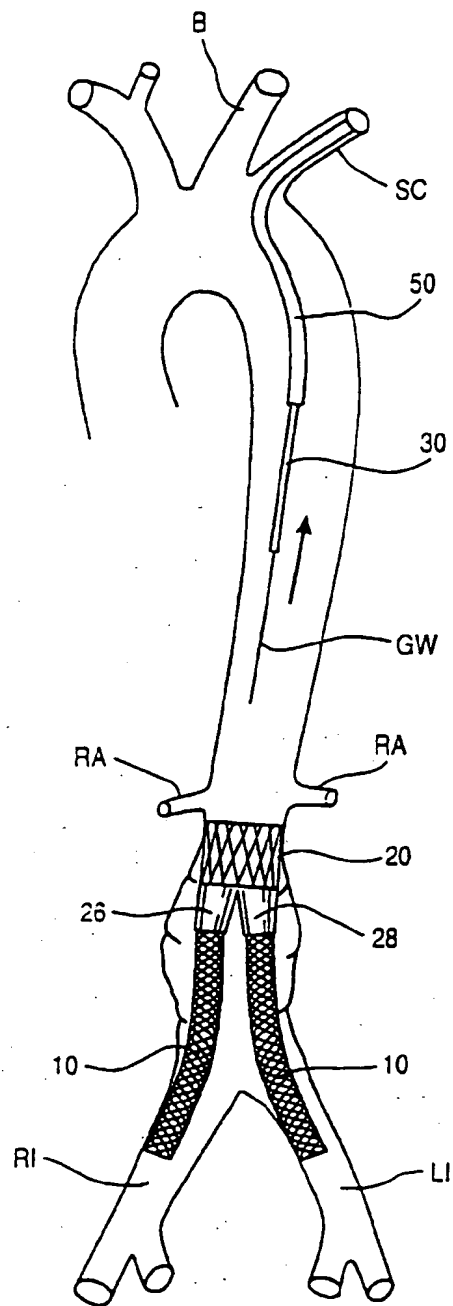


FIG. 12